

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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BIOGEN INC. and UNIVERSITY OF)
ZÜRICH,
Plaintiffs,)
v.) C.A. No. _____
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CREATIVE BIOLABS INC.) JURY TRIAL DEMANDED
)
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Defendant.)
)
)

COMPLAINT

Plaintiffs Biogen Inc. (“Biogen”) and the University of Zürich (“UZH”) for their Complaint against defendant Creative Biolabs Inc. (“Defendant”) alleges as follows:

NATURE OF ACTION

1. Plaintiffs Biogen and UZH bring this action under the federal patent and trademark laws as well as Massachusetts state law to stop Defendant from unlawfully selling purported copies of an innovative therapeutic antibody for treatment of Alzheimer’s disease developed by Biogen at a cost of hundreds of millions of dollars. Defendant’s willful infringement of Biogen and UZH’s intellectual property rights threatens to cause irreparable injury both to Biogen and to investigators who might mistakenly use Defendant’s unauthorized copycat products in their scientific and clinical research.

THE PARTIES

2. Biogen is a world-renowned innovator in neuroscience. Biogen leads scientific research and development to create new, lifesaving treatments for devastating neurological and

neurodegenerative diseases, including multiple sclerosis, Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis (ALS). Biogen invests over \$2.5 billion annually on research and development. Its world headquarters are located at 225 Binney Street, Cambridge, Massachusetts 02142.

3. The University of Zürich is a Swiss university dedicated to excellence in research, outstanding teaching, and services for the public. UZH was founded in 1833. It was the first university in Europe established by a democratic state and without ecclesiastical or royal patronage. It is located at Ramistrasse 71, CH-8006 Zürich, Switzerland.

4. On information and belief, defendant Creative Biolabs has a principal place of business at 45-1 Ramsey Road, Shirley, New York 11967. On its internet website, Defendant represents that it is a "custom service provider" focused in the "antibody production and engineering fields."

5. On information and belief, a multitude of related entities also operate at 45 Ramsey Road in Shirley, New York under the same management and control as Defendant. These entities are doing business under corporate names that include Creative Biomart, Creative Biogene, Creative Proteomics, Creative Bioarray, Profaegen, CD Bioscience, and CD Genomics.

JURISDICTION AND VENUE

6. This action for patent and trademark infringement arises under 35 U.S.C. § 271 and 15 U.S.C. § 1125, respectively.

7. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a) because this is a civil action arising both under the Patent Act and the Lanham Act.

8. This Court has supplemental jurisdiction over Biogen's claims arising under the laws of Massachusetts pursuant to 28 U.S.C. § 1337(a) because they are substantially related to their federal claims and arise out of the same case or controversy.

9. Venue lies in this District pursuant to 28 U.S.C. § 1331(b) and (c) because Defendant, on information and belief, regularly conducts business in this District and advertises, offers for sale, and sells its infringing products in this District through a website available to residents of this District.

10. This Court has personal jurisdiction over Defendant because, on information and belief, (1) Defendant regularly and continuously transacts business within Massachusetts, including by soliciting business for its antibodies and other products in Massachusetts, either on its own or through an affiliate; (2) Defendant offers to sell and/or sells infringing products in Massachusetts to Massachusetts residents; (3) Defendant infringes Biogen's trademarks in Massachusetts; and (4) Defendant confusingly advertises the infringing products in Massachusetts.

FACTUAL BACKGROUND

11. As one of the world's first biotechnology companies, Biogen was founded in 1978 by Nobel Prize winners Walter Gilbert, Ph.D. and Phillip Sharp, Ph.D., together with Charles Weissmann, M.D., Ph.D., Heinz Schaller, Ph.D., and Sir Kenneth Murray, Ph.D.

12. Biogen pioneers innovations in neuroscience. Today, Biogen offers the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics, and conducts advanced research and development programs in multiple sclerosis and neuroimmunology,

neuromuscular disorders, movement disorders, Alzheimer's disease and dementia, ophthalmology, immunology, neurocognitive disorders, acute neurology, and pain.

13. Biogen has received global public recognition for its commercialized therapeutic products and its therapies in development.

14. Biogen is trusted by doctors, patients, regulatory agencies, and scientific researchers for its pioneering discoveries, innovations, clinical studies, and life-saving treatments.

15. Biogen has spent decades building national and international recognition around its brands and earning the trust of patients, providers, researchers, and regulatory agencies.

A. Overview of aducanumab

16. Biogen's aducanumab is an anti-amyloid beta human monoclonal antibody being investigated for the treatment of early Alzheimer's disease. Alzheimer's disease is a devastating, progressive neurological illness that impairs the cognitive skills and independence of millions of people worldwide. Today, more than 5 million Americans and more than 40 million people worldwide are living with Alzheimer's disease and related dementias, and these numbers are growing. Today, there are no approved treatments to prevent, delay, or stop the progression of Alzheimer's disease.

17. Biogen is working toward novel approaches for the treatment of Alzheimer's disease. As part of this work, Biogen licensed aducanumab from the Swiss biopharmaceutical company Neurimmune Therapeutics AG, pursuant to a collaborative development and license agreement, in order to support clinical development and commercialization of aducanumab. Neurimmune had licensed the technology and intellectual property rights from UZH.

18. Since October 2017, Biogen and the pharmaceutical company Eisai have collaborated on the clinical development and commercialization of aducanumab globally.

19. Biogen uses the designation “BIIB037” both internally and externally to signify aducanumab.

20. Biogen is currently pursuing regulatory approval, through the U.S. Food and Drug Administration, of aducanumab for treatment of early Alzheimer’s disease. Aducanumab targets aggregated forms of amyloid beta found in the brains of people with Alzheimer’s disease in the hopes of reducing their buildup. If approved, aducanumab would become the first therapy available in the United States to reduce the clinical decline of Alzheimer’s disease.

21. Biogen’s aducanumab has been the subject of significant public attention and media coverage. If approved, approximately 10 million Americans suffering from Alzheimer’s disease might qualify for treatment with aducanumab.

22. Biogen regularly seeks patent protection in the United States and globally for inventions arising from its research and development efforts. Patents are critical to Biogen’s business and its ability to attract investment capital, allowing Biogen to obtain and protect exclusive rights in its products and product candidates, including aducanumab.

B. The patent-in-suit

23. On December 9, 2014, the U.S. Patent Office duly issued U.S. Patent No. 8,906,367 (the “’367 patent”), titled “Method of providing disease-specific binding molecules and targets.” The ’367 patent includes both composition and method claims. A true and correct copy of the ’367 patent is attached as Exhibit A.

24. UZH is the assignee of the ’367 patent. Biogen exclusively licenses the ’367 patent.

25. The '367 patent discloses detailed information to the public concerning the composition and manufacture of aducanumab, including specific amino acid sequence information for the antibody.

26. The claims of the '367 patent are valid, enforceable, and not expired.

27. Aducanumab and methods of making aducanumab fall within the scope of the claims of the '367 patent, including at least claims 1-6 and 16.

C. Biogen's marks

28. In addition to obtaining patent protections, Biogen possesses federally registered marks as well as common law marks in the proprietary names it assigns to its products and product candidates. Biogen uses both its registered and unregistered marks in interstate commerce. Through these uses, Biogen has built up goodwill and value associated with its marks.

29. Biogen has a federally registered trademark for its logo used in connection with various products sold across the globe. For example, in addition to its various common law marks, Biogen owns a valid trademark registration (Reg. No. 4965489).



30. In addition to Biogen's use of this registered mark and specific marks for approved products, Biogen names product candidates in development using a "BIIB" designation. BIIB is Biogen's NASDAQ stock ticker abbreviation. Biogen's "BIIB" designation helps indicate Biogen's ownership rights and its goodwill.

31. Biogen engages in interstate activities designed to promote its products and product candidates as well as the goodwill associated with its marks throughout the United States.

32. Biogen uses the designation BIIB037 in its communications concerning aducanumab. For example, Biogen uses the designation BIIB037 when describing its product candidate aducanumab on its website, in communications with investors and regulatory agencies, in scientific documents, and in press releases.

33. Biogen disseminates aducanumab to clinical investigators for use only in the context of strictly-controlled clinical trials.

34. Biogen distributes written materials in clinical trials for aducanumab to investigators, including detailed clinical trial protocols. These materials use the designation BIIB037 to identify the antibody. Prospective and enrolled patients in clinical trials across the United States also receive materials using the designation BIIB037 for aducanumab. For example, subjects enrolling in clinical trials for “aducanumab (BIIB037)” must complete signed consent forms to enroll in the study, in which they receive materials with the “aducanumab (BIIB037)” designation.

D. Defendant’s sale of infringing aducanumab copycat products

35. Although Defendant touts itself as a biotechnology company “developing novel antibodies,” its website confirms that it is brazenly copying patented commercial products and products in development to offer for sale on its websites, including the websites www.creative-biolabs.com and www.creativebiolabs.net.

36. On these websites, Defendant advertises and offers to sell Biogen's patented antibody aducanumab, including identification of the antibody using Biogen's propriety designation BIIB037.

37. Defendant offers for sale at least numerous aducanumab products on its website, including two for which Defendant lists "BIIB037" on its website as an alternate name for the product:

- "Afuco™ Anti-APP ADCC Therapeutic Antibody (Aducanumab), ADCC Enhanced (CAT#: AFC-TAB-717)" ("AFC-TAB-717"); and
- "Anti-APP Therapeutic Antibody (Aducanumab) (CAT#: TAB-717)" ("TAB-717").

38. A true and correct copy of Defendant's online datasheet for AFC-TAB-717 is available at <https://www.creativebiolabs.net/pdf/AFC-TAB-717.pdf> and attached as Exhibit B.

39. A true and correct copy of Defendant's online datasheet for TAB-717 is available at <https://www.creativebiolabs.net/pdf/TAB-717.pdf> and attached as Exhibit C.

40. In addition to AFC-TAB-717 and TAB-717 discussed above, Defendant also advertises and offers to sell on its website Biogen's patented antibody aducanumab labeled with various fluorescent dyes. These products include:

- "Aducanumab-Alexa 350 (ADC-FL-127)" ("ADC-F-127")
- "Aducanumab-Alexa 405 (ADC-FL-128)" ("ADC-FL-128")
- "Aducanumab-Alexa 488 (ADC-FL-129)" ("ADC-FL-129")
- "Aducanumab-Alexa 532 (ADC-FL-130)" ("ADC-FL-130")
- "Aducanumab-Alexa 546 (ADC-FL-131)" ("ADC-FL-131")
- "Aducanumab-Alexa 555 (ADC-FL-132)" ("ADC-FL-132")

- “Aducanumab-Alexa 568 (ADC-FL-133)” (“ADC-FL-133”)
- “Aducanumab-Alexa 594 (ADC-FL-134)” (“ADC-FL-134”)
- “Aducanumab-Alexa 647 (ADC-FL-135)” (“ADC-FL-135”)
- “Aducanumab-Alexa 680 (ADC-FL-136)” (“ADC-FL-136”)
- “Aducanumab-Alexa 750 (ADC-FL-137)” (“ADC-FL-137”)
- “Aducanumab-Bodipy FL (ADC-FL-138)” (“ADC-FL-138”)
- “Aducanumab-Coumarin (ADC-FL-139)” (“ADC-FL-139”)
- “Aducanumab-Cy3 (ADC-FL-140)” (“ADC-FL-140”)
- “Aducanumab-Cy5 (ADC-FL-141)” (“ADC-FL-141”)
- “Aducanumab-Fluorescein (ADC-FL-142)” (“ADC-FL-142”)
- “Aducanumab-OGreen (ADC-FL-143)” (“ADC-FL-143”)
- “Aducanumab-PBlue (ADC-FL-144)” (“ADC-FL-144”).

41. A true and correct copy of Defendant’s online data sheet for ADC-FL-127 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-127.pdf> and attached as Exhibit D.

42. A true and correct copy of Defendant’s online data sheet for ADC-FL-128 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-128.pdf> and attached as Exhibit E.

43. A true and correct copy of Defendant’s online data sheet for ADC-FL-129 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-129.pdf> and attached as Exhibit F.

44. A true and correct copy of Defendant’s online data sheet for ADC-FL-130 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-130.pdf> and attached as Exhibit G.

45. A true and correct copy of Defendant’s online data sheet for ADC-FL-131 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-131.pdf> and attached as Exhibit H.

46. A true and correct copy of Defendant's online data sheet for ADC-FL-132 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-132.pdf> and attached as Exhibit I.

47. A true and correct copy of Defendant's online data sheet for ADC-FL-133 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-133.pdf> and attached as Exhibit J.

48. A true and correct copy of Defendant's online data sheet for ADC-FL-134 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-134.pdf> and attached as Exhibit K.

49. A true and correct copy of Defendant's online data sheet for ADC-FL-135 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-135.pdf> and attached as Exhibit L.

50. A true and correct copy of Defendant's online data sheet for ADC-FL-136 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-136.pdf> and attached as Exhibit M.

51. A true and correct copy of Defendant's online data sheet for ADC-FL-137 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-137.pdf> and attached as Exhibit N.

52. A true and correct copy of Defendant's online data sheet for ADC-FL-138 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-138.pdf> and attached as Exhibit O.

53. A true and correct copy of Defendant's online data sheet for ADC-FL-139 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-139.pdf> and attached as Exhibit P.

54. A true and correct copy of Defendant's online data sheet for ADC-FL-140 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-140.pdf> and attached as Exhibit Q.

55. A true and correct copy of Defendant's online data sheet for ADC-FL-141 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-141.pdf> and attached as Exhibit R.

56. A true and correct copy of Defendant's online data sheet for ADC-FL-142 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-142.pdf> and attached as Exhibit S.

57. A true and correct copy of Defendant's online data sheet for ADC-FL-143 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-143.pdf> and attached as Exhibit T.

58. A true and correct copy of Defendant's online data sheet for ADC-FL-144 is available at <https://www.creative-biolabs.com/adc/pdf/adc-fl-144.pdf> and attached as Exhibit U.

59. Defendant's website includes an "overview" in marketing its aducanumab products, stating that "aducanumab, (also known as BIIB037) . . . has been used in trials studying the treatment of Alzheimer's disease." Defendant states that aducanumab is being developed by Biogen and cites Biogen's clinical trials as evidence of its applicability to the treatment of Alzheimer's disease. Defendant further purports to provide purported "high-quality aducanumab." See <https://www.creativebiolabs.net/aducanumab-overview.htm>. A true and correct copy of Defendant's "Aducanumab Overview" is attached as Exhibit V.

60. Through its website, Defendant advertises its purported expertise in manufacturing and selling aducanumab. It publicly claims to offer aducanumab for sale to researchers to support their research projects on Alzheimer's disease.

61. Defendant issued a press release in October 2019 touting its aducanumab antibody. A true and correct copy of this press release is attached as Exhibit W.

62. Defendant does not disclose information regarding the purity of its aducanumab products or its manufacturing processes. On information and belief, however, Defendant does not manufacture its aducanumab products using the same rigorous manufacturing controls that Biogen uses to make its patented aducanumab product. Accordingly, the sale of Defendant's purported aducanumab, on information and belief, would pose a likely public health hazard if it were confused with the aducanumab Biogen manufactures for its clinical trials.

63. In using the aducanumab and/or BIIB37 designation for these antibodies and in associating its aducanumab with Biogen's clinical development of aducanumab, Defendant confusingly and deceptively represents to the public and its potential customers that AFC-TAB-717, TAB 717, and ADC-FL-127, ADC-FL-128, ADC-FL-129, ADC-FL-130, ADC-FL-131, ADC-FL-132, ADC-FL-133, ADC-FL-134, ADC-FL-135, ADC-FL-136, ADC-FL-137, ADC-FL-138, ADC-FL-139, ADC-FL-140, ADC-FL-141, ADC-FL-142, ADC-FL-143, and ADC-FL-144 have the same properties as Biogen's BIIB037.

64. AFC-TAB-717, TAB 717, and ADC-FL-127, ADC-FL-128, ADC-FL-129, ADC-FL-130, ADC-FL-131, ADC-FL-132, ADC-FL-133, ADC-FL-134, ADC-FL-135, ADC-FL-136, ADC-FL-137, ADC-FL-138, ADC-FL-139, ADC-FL-140, ADC-FL-141, ADC-FL-142, ADC-FL-143, and ADC-FL-144 infringe the '367 patent, including at least claims 1-6, and 16.

65. By using BIIB037 and "Biogen" in connection with the advertising and sale of its purported aducanumab products, Defendant is violating Biogen's trademark rights.

66. On October 18, 2019 Biogen sent a letter via U.S. registered mail to Defendant at its headquarters and to its registered agent in New York. Biogen demanded that Defendant stop manufacturing, having others manufacture, offering for sale, and selling Biogen products, and also that it remove all references to Biogen tradenames or products from its website. Counsel for Biogen also called and emailed Defendant seeking a response to the October 18, 2019 letter.

67. Defendant never responded to Biogen's letter, calls or emails.

COUNT I
(Infringement of the '367 Patent)

68. Biogen and UZH repeat and reallege the allegations contained in paragraphs 1 to 67 above as if fully set forth herein.

69. Defendant represents in its advertising and marketing materials that AFC-TAB-717, TAB 717, and ADC-FL-127, ADC-FL-128, ADC-FL-129, ADC-FL-130, ADC-FL-131, ADC-FL-132, ADC-FL-133, ADC-FL-134, ADC-FL-135, ADC-FL-136, ADC-FL-137, ADC-FL-138, ADC-FL-139, ADC-FL-140, ADC-FL-141, ADC-FL-142, ADC-FL-143, and ADC-FL-144 are aducanumab, including with the alternative name BIIB037, a proprietary designation used by Biogen for its patented aducanumab.

70. Biogen's aducanumab is covered by at least claims 1-6 and 16 of the '367 patent.

71. Defendant therefore has infringed and continues to infringe, literally or by doctrine of equivalents, one or more claims of the '367 patent, including but not limited to claims 1-6, and 16, by making, offering to sell, importing, and/or selling into the United States AFC-TAB-717, TAB 717, and ADC-FL-127, ADC-FL-128, ADC-FL-129, ADC-FL-130, ADC-FL-131, ADC-FL-132, ADC-FL-133, ADC-FL-134, ADC-FL-135, ADC-FL-136, ADC-FL-137, ADC-FL-138, ADC-FL-139, ADC-FL-140, ADC-FL-141, ADC-FL-142, ADC-FL-143, and ADC-FL-144.

72. Biogen and UZH have been and continue to be damaged by Defendant's infringement, in an amount to be proven at trial.

73. Defendant's infringement is irreparably harming Biogen and UZH and will continue to do so unless enjoined.

74. Upon information and belief, Defendant's infringement has been and continues to be willful, entitling Biogen and UZH to treble damages and attorneys' fees.

COUNT II
(False Description and Designation of Origin (§ 1125(a)))

75. Biogen repeats and realleges the allegations contained in paragraphs 1 to 74 above as if fully set forth herein.

76. Biogen's BIIB037 mark identifies aducanumab as originating from Biogen, a world-renowned pioneer in neuroscience treatment.

77. Biogen owns all rights, including all common law rights, in the term "BIIB037" for its antibody aducanumab, and Biogen has continuously used BIIB037 externally to investors, regulatory agencies, researchers, clinicians, and the public.

78. Defendant has used and is continuing to use in commerce the BIIB037 designation in connection with its infringing aducanumab products. This use is likely to cause confusion or mistake, or to deceive as to the origin, sponsorship, or approval of Defendant's goods and/or misrepresents the nature, characteristics, qualities, or origin of Defendant's goods.

79. Defendant's use of the BIIB037 mark has caused, and/or is likely to cause, confusion and mistake, and/or to deceive the public, including clinical trial investigators and researchers, to the detriment of public health and safety.

80. Upon information and belief, Defendant's infringement has been and continues to be willful.

81. Biogen has been and continues to be damaged by Defendant's infringement, in an amount to be proven at trial.

82. Defendant's infringement is irreparably harming Biogen and will continue to do so unless enjoined.

COUNT III
(Unfair Competition -- M.G.L. ch. 93A)

83. Biogen repeats and realleges the allegations contained in paragraphs 1 to 82 above as if fully set forth herein.

84. Biogen and Defendant are persons engaged in the conduct of trade or commerce within the meaning of Mass. Gen. Laws ch. 93A, § 11.

85. Biogen's BIIB037 mark identifies aducanumab as originating from Biogen, a world-renowned pioneer in neuroscience treatment.

86. Defendant's practices as described above, including its violations of the Lanham Act, constitute willful and knowing violations of M.G.L. ch. 93A, §11. These violations include, but are not limited to, Defendant's continued offer for sale, marketing, and advertisement of its copycat aducanumab product and wrongful use of Biogen's BIIB designation and "Biogen" in connection with its sales, marketing, and advertising.

87. Defendant has intentionally, and wrongfully, deceived and continues to deceive the public by indicating that it has the authority to manufacture, market, advertise, distribute, and sell Biogen's patented aducanumab and use the BIIB037 designation when, in fact, it does not.

88. Defendant's use of the BIIB037 mark in connection with the sale of its infringing products has caused, and/or is likely to cause, confusion and mistake, and/or to deceive the public including clinical trial investigators and researchers, to the detriment of public health and safety.

89. Defendant's deceptive conduct constitutes unfair methods of competition.

90. As a result of Defendant's violation of Chapter 93A, Biogen has been damaged and will continue to be damaged.

91. In addition, under M.G.L. ch. 93A, Defendant owes Biogen reasonable attorneys' fees and treble damages in amounts to be determined at trial.

PRAYERS FOR RELIEF

WHEREFORE, Biogen and UZH respectfully request the following relief:

- a. A judgment declaring that Defendant has infringed the '367 patent, and that Defendant's making, using, selling, offering to sell, or importing of its purported aducanumab products directly infringes the '367 patent;
- b. A permanent injunction enjoining Defendant and any individual or entity acting on its behalf from infringing the '367 patent;
- c. A permanent injunction enjoining Defendant and any individual or entity acting on its behalf from any advertising, offering to sell, manufacturing, or selling its purported aducanumab products and/or any Biogen products;
- d. An order directing Defendant to deliver to Biogen and UZH an accounting of all infringing products manufactured or sold, and to supply Biogen and UZH with a complete accounting of any and all sources and processes for manufacture of the infringing products;
- e. A judgment holding that Defendant has infringed Biogen's marks in violation of 15 U.S.C. § 1125;
- f. A permanent injunction enjoining Defendant and any individual or entity acting on its behalf from infringing the BIIB037 mark;
- g. An order directing Defendant to remove all references to Biogen, BIIB, or Biogen tradenames from Defendant's website and any other marketing materials belonging to Defendant and any individual or entity acting on its behalf;
- h. Monetary damages in an amount to be proven at trial for the economic injury sustained as a consequence of Defendant's actions, together with pre-judgment and post-judgment interest;
- i. Attorneys' fees and costs in this action; and
- j. Such further and other relief as the Court deems just and proper.

JURY DEMAND

Biogen and UZH demand trial by jury on all claims and issues so triable.

BIOGEN INC., and UNIVERSITY OF ZÜRICH

By their attorneys,

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